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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,314	06/29/2000	Richard Fike	0942.4290005/RWE/BJD	1340

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EXAMINER
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FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/606,314

Applicant(s)

FIKE ET AL

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27,36,92-95,103 and 110-121 is/are pending in the application.
- 4a) Of the above claim(s) 112-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,36,92-95,103 and 111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, Claims 27, 36, 92-95 and 103 in the reply filed on September 24, 2004 is acknowledged. Further acknowledgment is made of Applicant's election of the species, animal cell, in the reply filed on November 22, 2005.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

The claims have been examined, insofar, as they read on the elected invention.

**Claims 27, 36, 92-95, 103 and 111 are under examination.**

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

Claims 27, 36, 92-95, 103 and 111 remain/is rejected under 35 U.S.C. 102(b) as being anticipated by Pebbles (A\*) and Getler et al. (AB4), as evidenced by the teachings of Fassolitis et al. (U). Each of Applicant's arguments has been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims an agglomerated eukaryotic cell culture medium powder prepared by agglomerating a dry powder eukaryotic cell culture medium with a solvent; wherein said agglomerated powder, upon being reconstituted with water, supports the

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cultivation of a eukaryotic cell *in vitro*. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits more rapid dissolution in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium powder of any one of claims 92-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said solvent is water, serum, aqueous acid or base. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said eukaryotic cell is an animal cell.

Applicant's main argument is directed to the idea that the teachings of Peebles and Getler in view of the other prior art references fail to provide a clear and convincing teaching that the milk products of either Peebles or Getler are inherently capable of supporting the growth of a eukaryotic cell *in vitro*. However, Applicant's arguments are not persuasive because Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. See Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than

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the particle size of the original powder, is readily dispersible in water, and has reduced dusting. See claims and Column 9, lines 46-54. Furthermore, Getler teaches agglomerated milk products and milk-like products which are made in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (see page 1, lines 11-14); and a fat component mixed with water, vitamins, and with raw materials in powder form, *i.e.*, casein, whey, skim milk, malto dextrine, *etc.* See page 1, line 36 to page 7, line 2. In Example 3, Getler teaches an agglomerated powder that exhibits reduced dusting and rapid dissolution.

With regard to the claim limitation "wherein said agglomerated powder upon being reconstituted with water supports the cultivation or proliferation of a eukaryotic cell *in vitro*" of Claim 1, the referenced agglomerated powders taught by Peebles and Getler are deemed to inherently possess the claim-designated limitation because it is notoriously old and well known in the art of microbiology that milk and milk products contain the appropriate components to allow the proliferation of eukaryotic cells, as evidenced by the teachings of Fassolitis. For example, Fassolitis teaches a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells, using a powdered nonfat dry skim milk filtrate (NDMF) as a eukaryotic cell culture medium. See page 201, Column 1, under "Preparation of milk fraction", wherein Fassolitis teaches a method of making NDMF comprising reconstituting a dry milk powder. On page 200, Column 2,

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under "Cell culture medium", Fassolitis teaches a cell culture medium supplemented with 5% NDMF, and adjusted to a pH of 6.8 to 7.4 that is used to propagate epithelial cells (see Table 1 on page 201). Thus, as evidenced by Fassolitis, the prior art agglomerated dry powders taught by Peebles and Getler are deemed agglomerated eukaryotic cell culture medium powders that are able to support the proliferation of a eukaryotic cell *in vitro* upon reconstituted with water and inherently have the claim-designated pH range.

Nonetheless, Applicant argues, "However, Fassolitis in no way demonstrates that the particular agglomerated dried milk of *Peebles* or *Getler* is capable of supporting the cultivation or proliferation of a eukaryotic cell *in vitro*. Rather, Fassolitis only states that a mixture of 50% Leibovitz L-15 medium and 50% Eagle minimal essential medium containing L-glutamine, nonessential amino acids, Hanks salts, 0.0.375% sodium bicarbonate, and 20 mM HEPES buffer, *and merely supplemented with 5% NDMF as a substitute for serum* is capable of supporting the growth of an epithelial cell *in vitro*." Thus, Applicant concludes that neither *Peebles* nor *Getler* teach that a liquid obtained by adding water to the referenced agglomerated dry milk compositions can be used as a culture media. Applicant's arguments have been thoroughly considered. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the instantly claimed invention. For instance, the limitations of independent Claim 27 does not encompass a liquid obtained by the addition of water to the claim-designated product-by-process agglomerated eukaryotic cell medium powder that can be used as a culture medium. The scope of the claimed invention only

encompasses a product-by-process agglomerated eukaryotic cell medium powder, which upon being reconstituted with water *supports* proliferation of a eukaryotic cell *in vitro*. Because neither Peebles nor Getler expressly taught that the referenced agglomerated dry milk powders as an agglomerated cell culture medium (with particular regard to the agglomerated dried skim milk powder taught by Peebles), the Office relied on the teachings of Fassolitis to provide evidence that at time the invention was made it was old and well-known in the art of tissue culture that nonfat dry milk powder when upon being reconstituted with a solvent, such as water, could be used to *support* proliferation of a eukaryotic cell *in vitro*. For example, on page 200, Column 1, in its entirety, Fassolitis expressly teaches that a number of milk types and milk fractions, especially skim milk products, were known in the art of tissue culture to *support* the proliferation of eukaryotic cells *in vitro*. Moreover, Fassolitis expressly teaches a method of supporting the proliferation of eukaryotic cells *in vitro* comprising culturing epithelial cells in a culture medium supplemented with a skim-milk powdered product. Furthermore, while limitations cannot be read into the claims for interpreting the scope of a claimed invention, the Office can look to the specification to determine the meanings of the terms recited therein the body of a claim. Thus, with regard to the meaning of the recited claim language of “wherein said agglomerated powder, upon being reconstituted with water” or “wherein said medium is reconstituted with a solvent”, the Office looks to the disclosure of Applicant’s specification to ascertain the meaning of the terms. For example, at page 33, lines 20-27, Applicant discloses that reconstitution of a cell culture medium can encompass the addition of water, serum, organic solvents,

or any combination thereof, any of which may contain one or more additional components or supplements. Thus, while Applicant's arguments stress that the powdered milk product used by Fassolitis for the proliferation of eukaryotic cells *in vitro* is a mere supplement, the Office notes that even Applicant readily admits that Fassolitis teaches that the *NDMF* taught by Fassolitis *supports* the proliferation of eukaryotic cells *in vitro*. Thus, the Office holds that the agglomerated powder compositions taught by Peebles and Getler would indeed *support* the proliferation of eukaryotic cells *in vitro*, since Fassolitis teaches that powdered milks and milk fractions, particularly of skim-milk, *support* the proliferation of eukaryotic cells *in vitro*, absence evidence to the contrary, given that Fassolitis teaches that skim-milk dry powders or fractions thereof when combined with a solvent, such as the growth media comprising water and other components contained therein used to propagate the milk-grown cells. Please note that independent Claim 27, as drafted, does not preclude the addition of a solvent, such as water or serum comprising additional components, for the reconstitution of the claim-designated product-by-process agglomerated eukaryotic cell culture medium, wherein such reconstitution with water or a solvent *supports* proliferation of a eukaryotic cell *in vitro*.

The reference anticipates the claimed subject matter.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PRIMARY EXAMINER**

Michele Flood  
Primary Examiner  
Art Unit 1655

MCF  
February 6, 2006